



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0443; FRL-8850-01-OCSPP]

Octamethylcyclotetra-siloxane (D4); Draft Scope of the Risk Evaluation to be Conducted under the Toxic Substances Control Act; Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with implementing regulations for the Toxic Substances Control Act (TSCA), the Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on the draft scope of the risk evaluation to be conducted for octamethylcyclotetra-siloxane (D4). D4 (Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-; Chemical Abstracts Service Registry Number (CASRN) 556-67-2), is a chemical substance for which EPA received a manufacturer request for risk evaluation. The draft scope for this chemical substance includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA plans to consider in conducting the risk evaluation for this chemical substance. EPA is also opening a 45-calendar day comment period on the draft scope to allow for the public to provide additional data or information that could be useful to the Agency in finalizing the scope of the risk evaluation; comments may be submitted to this docket.

DATES: Comments must be received on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0443, online using the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is

available at <https://www.epa.gov/dockets/about-epa-dockets>.

Due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room were closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Bethany Masten, Existing Chemical Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency (Mailcode 7404T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 564-8803; email address: masten.bethany@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

Supplementary Information

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to entities that manufacture (including import) a chemical substance regulated under TSCA, 15 U.S.C. 2601 *et seq.*, (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What is the Agency's authority for taking this action?

The draft scope of the risk evaluation is issued pursuant to TSCA implementing regulations at 40 CFR 702.41(c)(7).

C. What action is the Agency taking?

EPA is publishing and requesting public comment on the draft scope of the risk evaluation for D4 under TSCA. Through the risk evaluation process, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, as determined by the Administrator, in accordance with TSCA section 6(b)(4).

II. Background

TSCA allows chemical manufacturers to request an EPA-conducted risk evaluation of a chemical substance under 40 CFR 702.37. On March 19, 2020, EPA received a manufacturer request for a risk evaluation of D4. In the *Federal Register* notice of June 17, 2020 (85 FR 36586; FRL-10010-49), EPA opened a 45-day public comment period to gather information relevant to the requested risk evaluation. EPA granted the request on October 6, 2020, and subsequently initiated the scoping process for the risk evaluation for this chemical substance on November 5, 2020. The purpose of a risk evaluation is to determine whether a chemical substance, or group of chemical substances, presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation (15 U.S.C. 2605(b)(4)(A)). As part of this process, EPA must evaluate both hazards and exposures for the conditions of use; describe whether aggregate or sentinel exposures were considered and the basis for consideration; not consider costs or other non-risk factors; take into account where relevant, likely duration, intensity, frequency, and number of exposures; and describe the weight-of-scientific-evidence for hazards and exposures (15 U.S.C. 2605(b)(4)(F)). This process will culminate in a determination of whether or not the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use (15 U.S.C. 2605(b)(4)(A); 40 CFR 702.47).

III. Draft Scope of the Risk Evaluation for Octamethylcyclotetra-siloxane (D4)

The chemical substance for which EPA is publishing the draft scope of the risk evaluation is listed on the TSCA Inventory with CA Index Name “Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-” and the associated Chemical Abstracts Service Registry Number (CASRN) 556-67-2. The draft scope of the risk evaluation for this chemical substance includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA plans to consider in the risk evaluation (15 U.S.C. 2605(b)(4)(D)). Development of the scope is the first step of a risk evaluation. The draft scope of the risk evaluation will include the following components (40 CFR 702.41(c)):

- The conditions of use, as determined by the Administrator, that EPA plans to consider in the risk evaluation.
- The potentially exposed populations that EPA plans to evaluate; the ecological receptors that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.
- A description of the reasonably available information and the science approaches that the Agency plans to use.
- A conceptual model that will describe the actual or predicted relationships between the chemical substance, the conditions of use within the scope of the evaluation and the receptors, either human or environmental, with consideration of the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, to release or disposal—and identification of human and ecological health hazards EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.
- An analysis plan, which will identify the approaches and methods EPA plans to use to assess exposure, hazards, and risk, including associated uncertainty and variability, as well as a strategy for using reasonably available information and science approaches.
- A plan for peer review.

EPA encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. EPA will publish a notice in the *Federal Register* announcing the availability of the final scope of the risk evaluation within three months of publishing the draft scope.

Authority: 15 U.S.C. 2601 *et seq.*

Michael S. Regan,

Administrator.

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